TSRH® Spinal System
510(k) Summary

APR 30 2010

April 2010

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: **Brad Sheals**
Senior Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:** TSRH® Spinal System

III. **Classification Name(s):** Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System, and Pedicle Screw Spinal System (per 21CFR Section 888.3050, 888.3060, and/or 888.3070); Product Code(s): KWP, MNI, MNH, NKB

III. **Description:** The TSRH® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

The TSRH® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, staples, plates and connecting components as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other Medtronic spinal systems can be used with the TSRH® Spinal System. These components include GDLH® rods, GDLH® rod/bolt connectors, GDLH® Variable Angle T-Bolts, GDLH® set screws and locking screws, DYNALOK® PLUS™ bolts, CD HORIZON® Low Profile MULTI-SPAN® CROSSLINK® Plates, VANTAGE™ Anterior Fixation System screws, and CD HORIZON® rods, set screws and locking screws.

The hooks are intended for posterior use only and the staples are for anterior use only. The TSRH-3D® and TSRH-3Dx™ connectors and TSRH-3D® and TSRH-3Dx™ screws are intended for posterior use only. Within the TSRH® family, the cobalt chromium rods should only be used with TSRH® 3Dx™ Spinal System. All CROSSLINK® Plates are for posterior use and the CROSSLINK® Axial and Offset Plates may be used anteriorly as well.

The TSRH® Spinal System components are fabricated from medical grade stainless steel, medical grade titanium or titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy. Medical grade titanium, titanium alloy, and/or cobalt-chromium-molybdenum alloy may be used together. Certain TSRH® Spinal System components may be coated with hydroxyapatite. The subject components will be manufactured from medical grade titanium alloy described by such standards as ASTM F 136 or ISO 5832-3. The TSRH® Spinal System may be sold sterile or non-sterile.

The purpose of this 510(k) submission is to include hydroxyapatite coated screws into the TSRH® Spinal System.

IV. Indications for Use:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the TSRH® Spinal System is indicated as an adjunct to fusion for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated as an adjunct to fusion for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint: (2) who are receiving fusions using autogenous bone graft only: (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spondylolisthesis, (3) fracture, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) pseudarthrosis, (7) tumor resection, and/or (8) unsuccessful previous attempts at spinal fusion.

When used as a unilateral supplemental fixation device in the antero-lateral thoracic/lumbar region, the TSRH® L-Plate and VANTAGE™ screws are intended for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthritis; and/or failed previous fusion.

For anterior use only the TSRH® Spinal System has the additional indication of: spondylolysis.

V. Identification of the Legally Marketed Predicate Devices Use to Claim Substantial Equivalence: The design features, materials and indications for use of the TSRH® Spinal System are substantially equivalent to predicate TSRH® Spinal System components previously cleared in K081080 (S.E. 11/21/2008), K052054 (S.E. 08/16/2005) and predicate CD HORIZON® Spinal System components cleared in K043151 (S.E. 02/01/2005).

VI. Brief Discussion of the Non-Clinical Tests Submitted

For a determination of substantial equivalence, the following non-clinical mechanical tests were performed:

- Static Tensile Testing per ASTM F1147-05 (FDA Recognition No. 8-113)
- Average Coating Thickness Analysis per ASTM F1854-01 (FDA Recognition No. 8-85)

Existing testing was also provided to demonstrate the requirements of the FDA guidance document "510(k) Information Needed for Hydroxyapatite Coated Implants".

VII. Conclusions Drawn from the Non-Clinical Tests

Based on the supporting documentation within this premarket notification, the subject device demonstrates substantial equivalence to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 30 2010

Medtronic Sofamor Danek.USA
% Mr. Brad Sheals
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K091797
Trade/Device Name: TSRH® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: March 01, 2010
Received: March 02, 2010

Dear Mr. Sheals:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Bucher for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K091797

Device Name: TSRH® Spinal System

Indications for Use:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients using bone graft, the TSRH® Spinal System is indicated as an adjunct to fusion for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated as an adjunct to fusion for skeletally mature patients using bone graft: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint: (2) who are receiving fusions using autogenous bone graft only: (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spondylolisthesis, (3) fracture, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) pseudarthrosis, (7) tumor resection, and/or (8) unsuccessful previous attempts at spinal fusion.

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Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091797